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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/595,580 06/15/00 DOUGHERTY

E 4239-54279

EXAMINER

HM12/0702

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ART UNIT

PAPER NUMBER

1631

DATE MAILED:

07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/595,580

Applicant(s)

DOUGHERTY ET AL.

Examiner

Jerry Lin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 55-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-54 and 61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-54, 61, drawn to computer-implemented method for quantifying gene relatedness, classified in class 702, subclass 22.
 - II. Claims 55-60, drawn to a computer user interface, classified in class 345, subclass 326.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I is related to Invention II as processes and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case Invention I or II can be practiced by inputting information into a data processor and outputting the results on a paper printout. In addition Invention III does not actually practice the processes, but it merely displays the results of some processes. In addition, Invention II does not disclose any specific process of analysis of gene expression data and is applicable to any generic process. Invention II is not specifically related to Invention I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Gregory L. Maurer on February 13, 2001 a provisional election was made with traverse to prosecute the invention of a computer-implemented method for quantifying gene relatedness (Group I), claims 1-54, 61.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 55-60 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30, 33-54, 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "related" or "relatedness" has two different possible meanings. A set of related genes could mean a set of genes that are evolutionarily linked, however may not

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interact with each other. Alternatively, it could mean a set of genes that code for proteins that interact in a particular pathway. The examiner has taken to second meaning for purposes of this examination.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-54 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoughton *et al.* (Pat. 6,132,969) in view of Chapman *et al.* (Pat. 5,526,281) and further in view of Barnhill *et al.* (Pat. 5,769,074).

Stoughton *et al.* teach a generic method of predicting the responses of cellular constituents including mRNA to various forms of stimulus. He teaches inputting the

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data from observed levels of gene expression and creating a model based on the observed levels of gene expression to output the effects of cellular constituents (column 3, lines 29-33). It also tests for the effectiveness of the model by determining the overall goodness of fit and finding the cellular constituents with the strongest correlation (column 3, lines 37-45). Their model incorporates several perturbations such as the presence of a drug (column 7, lines 56-60), state of a cell (column 7, lines 29-31), and different levels of gene expression (column 7, 56-64). The model is compared to observed difference to test the goodness of fit or effectiveness (column 8, lines 37-40). A quantitative value is determined to indicate the overall goodness of fit (column 10, lines 29-30). Data for creating their model may come from a variety of well know sources, such a gene array or biochip (column 45, 10-16). Each set of data creates a several models, which is ranked in an influence matrix according to its degree of abstraction (column 9, lines 10-15). Each level of abstraction represents a set of cellular constituents (gene sets) from which the practitioner the model that best fits the observed data (column 9, lines 51-60). Their models may be implemented through either a truth table or another network model such as a neural network (column 19, line 35-40). The data in these models are found in ternary discrete values (column 20, table 3). Stoughton *et al.*'s method is embodied in computer software or hardwired into the hardware with graphical user interfaces (column 55, line 26- column 56 line 15).

However, Stoughton *et al.* does not explicitly teach using a neural network or displaying the results in the three-dimensional graph.

Chapman *et al.* teach the use of a learning neural network (artificial intelligence) in modeling biological activity and displaying data in three-dimensional graphs (see abstract; Fig 5a-c).

Barnhill *et al.* teach a method of using a neural network and decision tree to diagnose disease (column 26, lines 9-13).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use a neural network for Stoughton *et al.*'s method of predicting cellular responses. Stoughton *et al.*'s does suggest using other logic models to practice his invention. The neural network has advantages such the ability to create an artificial intelligence function. A three dimensional graph allows the practitioner to visually understand the results of this method. Thus a practitioner would be motivated to use the neural network for the logic model in Stoughton *et al.*'s method to create a more accurate and more understandable model.

It would also have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use a decision tree as suggested by Barnhill *et al.* with Stoughton *et al.*'s method. Stoughton *et al.*'s method includes predicting the responses of whole organisms. This would include a method of diagnosing patients as in Barnhill *et al.* Thus a practitioner would be motivated to incorporate Barnhill *et al.*'s method in order to incorporate a neural network and add the capability of diagnosing patients.

Information Disclosure Statement

8. Patent application 09/407021 has been considered but lined through on the attached PTO 1449 due to a lack of a date of publication

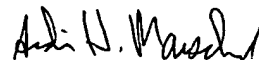
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (703) 306-5439. The examiner can normally be reached on 8:00am-4:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Jerry Lin
June 28, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER